K120354

MAR 2 1 2013

Skeletal Kinetics

A COLSON ASSOCIATE

510(k) Summary

General Information as required by 21 CFR 807.92 (a) (1)

Submitters Name/address:	Skeletal Kinetics® LLC
	10201 Bubb Road
	Cupertino, CA 95014, USA
Date:	March 18, 2013
Contact Person:	Christine Kuo,
	Director, Regulatory Affairs and Quality Assurance
	Phone: (408) 350-5842
	Fax: (408) 366-1077

Device Name as required by 21 CFR 807.92 (a) (2)

Trade Name:	Beta TCP Granules
Regulation Number:	21 CFR 888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	II
Product Code:	MQV

Predicate Devices as required by 21 CFR 807.92 (a) (3)

The subject device is substantially equivalent in safety and effectiveness to the following legally marketed device (predicate) – Cerasorb M Ortho (K040216).

Device Description as required by 21 CFR 807.92 (a) (4)

Beta TCP Granules Bone Void Filler is composed of porous, osteoconductive, resorbable beta- tricalcium phosphate (β-TCP) granules for repair of bony defects. The single use Beta TCP Granules sterile kit contains: Calcium Phosphate granules contained in a plastic

vial packaged within two industry standard peel pouches that provide a double sterile barrier.

Intended Use as required by 21 CFR 807.92 (a) (5)

Beta TCP Granules Bone Void Filler (BVF) is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Beta TCP Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Beta TCP Granules BVF will resorb and be replaced with bone during the healing process.

Summary of Technological Characteristics as required by 21 CFR 807.92 (a) (6)

Beta TCP Granules consists of beta-tricalcium phosphate (β-TCP) that can be applied directly to the intended sites. The intended use, and critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of Beta TCP Granules are substantially equivalent to the predicate device, Cerasorb M Ortho (K040216).

Summary of Non-clinical Tests as required by 21 CFR 807.92 (b) (1)

Critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of Beta TCP Granules were compared with those of Cerasorb M Ortho. Chemistry was determined by Fourier Transformed Infrared Spectroscopy (FTIR) and X-ray Diffraction (XRD) techniques. Both devices are composed of phase pure beta-tricalcium phosphate. Crystallinity was determined by X-ray Diffraction, and both materials consist of crystalline, phase-pure beta-tricalcium phosphate with no other crystalline or amorphous phases detected. Physical form was determined by Scanning Electron Microscopy, both devices are porous granules. The subject device is spherical in shape and the predicate device is composed of irregular granules. Porosity was determined by Mercury Intrusion Porosimetry, the interconnected porosity for both devices fall within a range porosities available in currently approved beta tricalcium phosphate bone void fillers. Solubility was measured by *in vitro* dissolution method measuring Ca^{2+} ion concentration in solution using Inductively Coupled Plasma – Atomic Emission Spectroscopy. Both devices demonstrated similar solubility profiles. Performance test results demonstrated

that Beta TCP has substantially equivalent critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) as the predicate device Cerasorb M Ortho (K040216).

Beta TCP Granules biocompatibility testing was performed in accordance with the standards set forth in ISO 10993-1, Biological Evaluation of Medical Devices and the test results demonstrated that Beta TCP Granules is biocompatible and meets the requirements of the ISO standards.

Beta TCP Granules will be provided as a single use, sterile product. The radiation dose of 25kGy - 40 kGy will be validated in accordance with ISO 11137-2006, Sterilization of Health Care Products - Radiation to Sterility Assurance Level (SAL) 10^{-6}.

The results of risk management indicate that the identified hazards were acceptable and/or mitigated to an acceptable level with the residual risk evaluation deemed as acceptable per defined procedures.

Non-clinical animal data in a large animal, cancellous bone defect model demonstrated that Beta TCP Granules is resorbed over time and allows bone ingrowth as the device is resorbing. Beta TCP Granules maintain the previously demonstrated safety profile of beta-TCP materials and is substantially equivalent to Cerasorb M Ortho (K040216).

Summary of Clinical Tests as required by 21 CFR 807.92 (b) (2)

Beta TCP Granules does not require clinical testing.

Conclusion as required by 21 CFR 807.92 (3)

The manufacturer compared the critical specifications - chemistry, crystallinity, physical form, porosity, dissolution/solubility of Beta TCP Granules with the predicate device. The results indicated that the device characteristics for Beta TCP Granules were the same as those of the predicate device. Non-clinical animal data in a large animal, cancellous bone defect model demonstrated that Beta TCP Granules is resorbed over time and allows bone ingrowth as the device is resorbing. Beta TCP Granules maintain the

previously demonstrated safety profile of beta-TCP materials and is substantially equivalent to Cerasorb M Ortho (K040216).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Skeletal Kinetics, LLC
% Ms. Christine Kuo
Director, Regulatory Affairs and Quality Assurance
10201 Bubb Road
Cupertino, California 95014

Re: K120354
Trade/Device Name: Beta TCP Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 8, 2013
Received: February 13, 2013

Dear Ms. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if Known): K120354

Device Name: Beta TCP Granules

Indications for Use:

Beta TCP Granules Bone Void Filler (BVF) is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Beta TCP Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Beta TCP Granules BVF will resorb and be replaced with bone during the healing process.

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-the-Counter Use (21CFR 801 Subpart C	____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K120354